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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,385	03/16/2001	Allen S. Laughon	WARF-0002	8778

26259 7590 06/14/2006

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,385

Applicant(s)

LAUGHON, ALLEN S.

Examiner

Alana M. Harris, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/12/05; 03/13/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 13, 2006 has been entered.

2. Claims 1-4 are pending.

Claim 4 has been amended.

Claims 1-4 are examined on the merits.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

3. The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicant's amendment.

Maintained Rejections

Claim Rejections - 35 USC § 112

4. The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained and newly made. **THIS IS A NEW MATTER REJECTION.**

Applicant had amended claim 1 to include the recitations, "TGF- β - dependent promoter..." and "expressing interacting proteins...". Furthermore, claim 2 has been amended to include the recitation "...expressing a Smad protein...". These claims still include new matter recitations "...reporter with a TGF- β -dependent promoter in cells expressing interacting proteins...":

Applicant asserts "[t]he basis for meeting the written description requirement is to convey to one of skill in the art that Applicant had possession of that which is claimed at the time the invention was made. MPEP 2163." And the Examiner was provided Su et al. to evidence the knowledge of one of skill in the art of screening assays at the time of filing of the present application, see Remarks submitted December 12, 2005, bridging paragraph of pages of 5 and 6. Applicant directs the Examiner's the attention page 15, lines 2-5; page 7, lines 24-28 and Figure 6. All of these citations allegedly support Applicant's claims. The Examiner has reviewed these passages, the Figure, as well as the Laughon Rule 132 declaration. It seems as if none of these sources provides

support for Applicant's amendment to claims 1 and 2. Clearly there is no support for a TGF- β -dependent promoter, expressing interacting proteins and repression of the said reporter within these sources.

Page 15, lines 2-5 prophetically note "...an assay...to detect changes in TGF- β -dependent reporter expression in response to specific compounds." It is assumed Applicant pointed to these lines, suggesting the said reporter expression lends supports to a TGF- β -dependent promoter. However, the recitation "TGF- β -dependent reporter expression" does not indicate that the promoter is exclusively a TGF- β -dependent promoter. Moreover, page 7, lines 24-28, as well as lines 12-19 does not mention an assay encompassing a promoter and the expression of interacting proteins by the cell. And Figure 3 and its caption found on page 6, lines 23-26 do not relay significant information about the promoter. There is a *wg-lacZ* reporter within the figure, but this in itself does not provide support for what is listed in Applicant's claims. And finally Exhibits A and B submitted with the Laughon declaration do not aid in supporting Applicant's claims. None of these passages, exhibits and figure list the reporter with a TGF- β -dependent promoter within cells expressing specifically interacting proteins with the detection of transcription and the comparison between levels of transcription at precise points. And the specification does not exemplify an experimental design of the claimed assay. The steps listed in the claims are not of record in the specification. The claims do not meet the written description requirement because the specification is remiss of active method steps including the cells containing interacting proteins and compounds necessitated for implementing the claimed method.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner can normally be reached on 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.

06 June 2006